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July 23, 1999

DOCKETS MANAGEMENT BRANCH (HFA-305)  
FOOD AND DRUG ADMINISTRATION  
5630 FISHERS LANE ROOM 1061  
ROCKVILLE, MD 20857-0003

RE: DOCKET NO. 98N-1265

To the FDA:

I am a person with AIDS. My partner also has AIDS and is without health insurance drug coverage: we are consumers of health care on a large scale, and pay for a lot of it out of pocket. I wish to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

I am concerned about both availability and cost of a range of drugs—and about patients' and doctors' ability to obtain information about drugs from pharmacists.

My partner needs to start testosterone supplementation to deal with side effects of AIDS medications. Under the MOU in its current form, his choice of testosterone formulations would be narrowed, his ability even to obtain information about them would be reduced, and his personal financial costs would be increased. This is only one current, personal example of the damaging effects the MOU in its present form would have.

The provisions for "gag" orders on pharmacists in the present form of the MOU should be abhorrent to anyone with a respect for free speech, regardless of political affiliation.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer I feel strongly that there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU must be amended!!!

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!

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New York

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